UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,396	08/31/2006	Stephen P. Goff	67489-PCT-US/JPW/JW	6298

23432 7590 07/22/2009

COOPER & DUNHAM, LLP
30 Rockefeller Plaza
20th Floor
NEW YORK, NY 10112

EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
07/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,396	GOFF ET AL.	
	Examiner	Art Unit	
	SAMUEL W. LIU	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,37 and 57-61* is/are pending in the application.

4a) Of the above claim(s) *37 and 58-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 February 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Status of claims

Claims 1-7, 37 and 57-61 are pending.

The amendment filed 4/13/09 which cancels claims 8-19, and adds claims 57-61 has been entered. Claims 20-36 and 38-56 were cancelled by the amendment filed 2/13/06.

Claim benefit

Applicant's claim for the benefit of a prior-filed application 60494764 filed 8/13/03 under 35 U.S.C. 119(e) is acknowledged. 60494764 has support for the elected invention (see below).

IDS

The references cited in the IDS filed 6/22/06 have been considered by Examiner.

Election/Restrictions

Applicants' election filed 4/13/09 of Group I, claims 1-7 with traverse is acknowledged. The traversal is on the ground(s) that Group I (pending claims 1-7) and Group III (pending claim 37) are related and not distinct from each other (note that claims 8-19 of Group II have been cancelled).

The instant application is a 371 application; the claimed ZAP protein does not constitute a special technical feature as defined by PCT Rule 13.2 and 37 CFR 1.475(a), as a single contribution over the art, and thus lack of unity (page 2, the Office action mailed 3/12/09). Furthermore, Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the ZAP protein can be utilized in a materially different processes, producing an antibody that specifically binds to the protein, for example. Thus, Groups I and III are patentably distinct from each other; and therefore. The requirement is still deemed proper and is therefore made FINAL.

New claims 58-61 are drawn to a process of using the ZAP protein. For the reasons stated above, the claims are drawn to the distinct invention, and thus, along with claim 37 (Group III) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b). Therefore, claims 1-7 are under examination.

Objection to specification

The disclosure is objected to because of the following informalities:

(1) At page 1, line 23 and 25, "PKR' and Mx" should be spelled out in full for the first instance of use. See also, page 2, line 4, ZAP"; page 8, line 9, "GAPDH".

(2) The specification cites references incorporated up to total "27" (see p.28, line 19); however, instant specification only set forth 19 references (see last page, i.e., p.31). The inconsistency in this regard must be clarified.

Objection to claim

In claim 7, "WWE region" should be changed to "WWE domain" for consistence with the specification (see page 12, lines 20 and 21).

Objection to drawings

The drawing (filed 2/13/06) of Fig. 3B is objected to because "CCCH Fingers" should be changed to "CCCH finger motifs" as set forth in the specification (p.7, lines 12 and 13) for consistency.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to **fully** comply with the requirements of 37 C.F.R. ∋ 1.821 through 1.825; Applicants' attention is directed to the final rule making notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

[1] At Figure 3B, the sequences of 4 amino acid sequences are disclosed without SEQ ID NO identification. See also "Notice to Comply".

[2] At page 19, lines 31 and 32, the sequences of one nucleotide sequence is disclosed without SEQ ID NO identification. See also "Notice to Comply".

[3] At page 20, lines 2 and 4-6, the sequences of three nucleotide sequences are disclosed without SEQ ID NO identification.

[4] At page 23, lines 8 and 9, the sequences of two nucleotide sequences are disclosed without SEQ ID NO identification.

[5] At page 24, lines 3-5, the sequences of two nucleotide sequences are disclosed without SEQ ID NO identification.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it

is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written description

Claims 1-4, 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors considered in the Written Description requirement are (1) Actual reduction to practice; (2) Disclosure of drawings or structural chemical formulas; (3) Sufficient relevant identifying characteristics; (4) Method of making the claimed invention; (5) Level of skill and knowledge in the art; and (6) Predictability in the art. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP § 2163.

Actual reduction to practice/Disclosure of drawings or structural chemical formulas.

Claim 1 and dependent claims 2-4, 6, and 7 therefrom as written are directed to **an** isolated ZAP protein. Without setting forth SEQ ID NO: or indicating that the claimed protein is a full-length polypeptide from certain species such as human, or/and reciting biological function thereof, the "**an** isolated ZAP protein" is drawn to a fragment or variant (genus) of the "ZAP" polypeptide, wherein said "genus" encompass mutations substitution, deletion or truncation and/or insertion and any subsequences of a full-length "ZAP polypeptide, and a biologically inactive variant thereof. The "ZAP" per se is a protein family (also a genus) comprising plurality of members characterized that every members have the CCCH-type zinc fingers; the "ZAP" may

have an activity of binding to RNA of a virus and inhibits replication thereof (p.12, lines 25-32, the specification). The specification fails to describe the fragment or the variant of "ZAP". Neither the specification nor the art in relative field provide representative members of said "variant" or/and "fragment" for the entire scope of the claims. The art teaches that a N-terminal truncation of a "CCCH-type tandem zinc-finger protein Zfp3612 results in loss-of-function (see abstract, and page 4891, left col. 2nd paragraph, Ramos et al. (2004) *Development*, 131, 4883-4893). This suggests that the fragment of variant of ZAP is biologically inactive including incapability of binding RNA and may lose activity of binding the viral RNA discussed above.

The court of Appeals for the Federal Circuit has held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] name chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". UC California v. Eli Lilly (43 USPQ2d 1398). For claims drawn to genus, MPEP section 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Also, MPEP section 2163 states that a representative number of species mean that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. Since instant specification fails to

describe the invention in such a way that one of ordinary skill in the art would recognize that applicants were in possession of the claimed method at the time the application was filed, applicants are not in possession of the claimed protein.

Sufficient relevant identifying characteristics

A sufficient/representative number of species of the "genus" is not disclosed. Neither the specification nor the art in the relative field describes/teaches the fragment of/and variant ZAP polypeptide having the biological activity. In the absence of direction and/or description of correlation between structure (core domain or consensus sequence) and function (e.g., inhibiting growth of RNA virus), applicants are not in possession of the claims.

Predictability in the art

The relative art teaches the truncation mutation causes loss-of-function of the CCCH-type zinc-finger polypeptide (see the above Ramos et al. teaching), suggesting that the level of unpredictability on the art is high.

Level of skill and knowledge in the art:

The general knowledge and level of skill in the art do not supplement the omitted description with respect to species which are representative of the genus discussed above. In the absence of the representative species for the full scope of the genus claimed, adequate written description requires more than a mere statement that it is part of the invention. Without a correlation between structure and function, the claims do little more than define the claimed invention by function. See *Eli Lilly*, 119, F.3d at 1568, 43USPQ2d at 1406. In this case, applicants do not describe the invention of claims 1-4, 6, and 7 as to structure of the

"variant"/"fragment" and the function such as inhibiting RNA viral growth adequately to show they has possession of the disclosed "genus" in the claimed product.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

CLAIM INTERPRETATION: Claim 1 as written is broadly directed to a protein named "ZAP" because claim 1 does not set forth structure and function of the claimed protein.

[1] Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatada et al. (US Pat. 6251620 B1).

Hatada et al teach a human "ZAP" protein called "ZAP NC" (col. 2, line 30), which anticipates claims 1 and 2.

[2] Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Babiychuk et al. (US2001/0011381 A1).

Babiychuk et al. teach a purified human PARP (see [0004]) which is a Zn-finger containing protein of ZAP family (class) (see [0020] and [0054]); i.e., PARP is a "ZAP" protein, which anticipates claims 1 and 2.

This "ZAP" protein can be obtained from not only human (*homo sapiens*) but also mouse (*Mus musculus of accession No.* **P111103**). This inherently anticipates claim 4 because of the following reason. The isolated protein having accession No. "P11103" is disclosed in article (Sallmann et al. (2000) *J. Biol. Chem.*, 275, 15504-15511, p.15507, 3rd paragraph, line 16, and in view of reference: NCBI (2009, updated) P11103, www.ncbi.nlm.nih.gov/protein/130782, pages 1-2; this reference provides a link between "P11103" and Sallmann et al.).

Claim Rejections - 35 USC §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al. (*Science* (2002, Sept.) 297, 1703-1706).

Gao et al. teach a lysate (a composition) comprising recombinantly-produced rat and mouse proteins comprising four potential CCCCH-type zinc-fingers (see Fig. 3B and page 1705,

left col. lines 1-10); said proteins have activity of inhibiting retroviral RNA production (see abstract and Fig. 4). Instant "ZAP" protein comprises four CCCH-type zinc-finger motifs and having activity of inhibiting RNA viral replication (p.12, lines 25-32, the specification); and thus, the Gao et al. teachings are applicable to claims 1, 3, and 4.

The amino acid sequence of the rat ZAP reads on instant SEQ ID NO:1 (see the SEQ alignment attachment II), as applied to claim 5.

Gao et al. do not expressly teach the isolated ZAP protein.

However, Gao et al. teach expression/production of the rZAP (rat ZAP) protein in L1D3 cells using expression vector (Fig.3, p. 1704 and 1705).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce the ZAP proteins including rZAP of SEQ ID NO:1. This is because Gao et al. have taught how to produce the ZAP protein via recombinant technology, and because Gao et al. also have taught great interest of using the (isolated) ZAP protein to test eliminating cytoplasmic fraction of the viral RNA and that the full-length Zap protein induces a dramatic inhibition of viral vector expression (see Fig.4 and p.1706, left col., lines 1-3 and lines 14-17). Furthermore, use of the recombinant technology to produce desirable protein is well within the purview of one of ordinary skill in the art such as "molecular biologist" when the instant invention was made. Thus, one of ordinary skill in the art would have readily tried to obtain the ZAP protein including SEQ ID NO:1 polypeptide *via* recombinantly expressing and isolating the protein with reasonable expectation of success. The isolated protein would be useful for investigating its role in inhibition of viral growth (see above). Therefore, the reference teaching renders the claimed product *prima facie* obvious.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

/Samuel Wei Liu/
Patent Examiner, Art Unit 1656

/ANAND U DESAI/
Primary Examiner, Art Unit 1656
July 19, 2009